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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,966	11/12/2003	Charles H. Pugsley	81614A	9418
23685	7590	08/30/2007		
KRIEGSMAN & KRIEGSMAN 30 TURNPIKE ROAD, SUITE 9 SOUTHBOROUGH, MA 01772			EXAMINER WOO, JULIAN W	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 08/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/712,966	Applicant(s) PUGSLEY ET AL.	
	Examiner Julian W. Woo	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-21 is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5-7 and 22-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on June 7, 2007 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent No. 6,692,507 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (6,620,194) in view of Yang et al. (6,258,121). Ding et al. discloses the invention substantially as claimed. Ding et al. disclose, at least in figure 9 and in col. 13, line 43 to col. 14, line 19 and col. 15, lines 1-4, a biocompatible fastener (101 and 106 combined) comprising a pair of members (101 and 106) matingly engageable with one

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another (via 102), where one the members comprises an outer coating (102) coated over a non-bioabsorbable (metal) material, where the outer coating comprises a first bioabsorbable material, where the inner core comprises the non-bioabsorbable material, where after the pair of members are matingly engaged with one another, degradation of the outer coating causes the pair of members to disengage from one another, and where only one of the members (101) comprises an outer coating coated over the inner core. However, Ding et al. do not specifically disclose that the first bioabsorbable material has a first degradation rate that is slower than a second degradation rate of a second bioabsorbable material of an inner core. Yang et al. teach, at least in col. 3, line 65 to col. 4, line 66 and col. 5, lines 38-65; an outer coating of a first bioabsorbable material (e.g., PLA /PEO) coated over an inner core (10 or 110) formed of non-bioabsorbable material (e.g., "metallic materials") or a second bioabsorbable material (e.g., PLA/PCL), where the degradation rate of the first absorbable material is faster than the degradation rate of the second bioabsorbable material. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the inner core of the device of Ding et al., in view of Yang et al., so that it is formed a second bioabsorbable material having a slower degradation rate than the first bioabsorbable material. Such an inner core formed of a bioabsorbable material would allow the scaffolding of a blood vessel, so that a therapeutic member or material can be first released into the diseased tissue before the patient's body absorbs both the inner core and outer coating.

Allowable Subject Matter

4. Claims 5-7 and 22-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a biocompatible fastener including, inter alia, a male member with a head and a female member with a bore and a flange, where at least one of the members includes an outer coating coated over an inner core, the outer coating comprising a first bioabsorbable material, the inner core comprising one of second bioabsorbable material and a non-bioabsorbable material, where after the members have been matingly engaged with one another, degradation of the outer coating over the inner core causes the members to disengage from one another.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

6. Claims 9-21 are allowed.

7. The following is an examiner's statement of reasons for allowance: The abovementioned terminal disclaimer overcomes the double patenting rejections in the Office action of March 2, 2007.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Amendment

8. The Examiner's indication of allowable subject matter in claims 1-7 and 22-27 is hereby withdrawn in view of the abovementioned new grounds of rejection and objection.

The abovementioned terminal disclaimer obviates the double patenting rejections in the Office action of March 2, 2007, and these rejections are hereby withdrawn.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Julian W. Woo". The signature is fluid and cursive, with the first name "Julian" being more prominent than the last name "Woo".

Julian W. Woo
Primary Examiner

August 28, 2007